510(k) Summary

Proprietary Name:	VariAx 2 System
Common Name:	Bone Screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030 Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	HRS: Plate, Fixation, Bone HWC: Screw, Fixation, Bone HTN: Washer, Bolt Nut
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Person:	Elijah N. Wreh Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 elijah.wreh@stryker.com Phone: 201-831-5691 Fax: 201-831-4691
Date Prepared:	August 7, 2013

OCT 2 3 2013

Description

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the VariAx 2 System. The VariAx 2 System is an internal fixation device consisting of screws and instrumentation that will be used in conjunction with previously cleared VariAx Plating Systems to treat a number of different types of fractures in the radius, ulna, humerus, clavicle, foot, ankle, distal tibia and fibula. These screws can be used in conjunction with said plating systems, or in the case of non-locking screws, may also be used independently using a lag screw technique. The subject components will be available sterile and non-sterile.

Intended Use

The Stryker VariAx 2 System is intended for internal bone fixation in adult patients.

Indications

The Stryker VariAx 2 System screws, when used in conjunction with VariAx Plating Systems; or used independently in a lag screw technique, are indicated for:

- Internal fracture fixation;
- Osteotomies;
- Revision procedures such as non-unions or mal-unions;

In addition, the following indications are specific to the devices listed below:

- T8 2.4mm Screws & T8 2.0mm Locking Peg: For use in small bones, primarily including the Distal Radius, in the treatment of:
  - Compression fractures;
  - Intra-articular and extra-articular fractures;
  - Displaced fractures;
  - Reconstruction procedures;

- T8 2.7mm Screws: For use in small bones, including the Distal Radius as well as the fore, mid- and hind Foot and Ankle, in the treatment of:
  - Intra-articular and extra-articular fractures of the Distal Radius,
  - Displaced and compression fractures of the Distal Radius;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Reconstruction procedures in the Foot & Ankle and Distal Radius;

- T10 3.5mm and T10 2.7mm Screws: For use in the Radius, Ulna, Clavicle, Humerus, Foot and Ankle, Distal Tibia and Fibula, in the treatment of:
  - Intra-articular and extra-articular fractures of the Distal Humerus and Proximal Ulna;
  - Single, segmental and comminuted fractures;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Normal bone density or osteopenic bone.

Summary of Technologies

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate devices:

Table 1: Predicate devices

510(k) Number	
K080667	VariAx Distal Radius Torx Screws
K100271	VariAx Distal Radius Line Extension of XXL Plates
K063875	Stryker Foot Plating System
K081284	VariAx Distal Fibula Plate
K102282	VariAx Locked Plating System Line Extension for Addition of Fibula Straight Plates
K073527	VariAx Elbow System
K101056	VariAx Elbow System
K113760	VariAx Clavicle System
K130009	VariAx 2 Compression Plating System
K000636	Stryker Trauma Plating System

Non-Clinical Testing

Non-clinical laboratory testing was performed for the VariAx 2 System components to determine substantial equivalence. Testing demonstrated that the VariAx 2 System is substantially equivalent to the predicate devices currently cleared for marketing.

The following testing was performed

- Screw Pull-Out Testing
- Screw Shear-Off Testing
- Screw Insertion Torque Testing
- Static Cantilever Bending of Locking Mechanism
- Dynamic Fatigue Plate-Screw Construct Testing

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The VariAx 2 System is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 23, 2013

Stryker Trauma AG
Mr. Elijah N. Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K132502
Trade/Device Name: VariAX 2 System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: August 7, 2013
Received: August 9, 2013

Dear Mr. Wreh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132502

Device Name: VariAx 2 System

Indications for Use:

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  - Intra-articular and extra-articular fractures of the Distal Radius,
  - Displaced and compression fractures of the Distal Radius;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Reconstruction procedures in the Foot & Ankle and Distal Radius;

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  - Intra-articular and extra-articular fractures of the Distal Humerus and Proximal Ulna;
  - Single, segmental and comminuted fractures;
  - Replantation, joint fusions or arthrodesis and corrective osteotomies in the Foot & Ankle;
  - Normal bone density or osteopenic bone.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices